

SEP 10 2003

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In re Application of :  
HERSHFIELD et al :  
Serial No.: 09/762,097 : Decision on Petition  
Filed: August 23, 2001 :  
Attorney Docket No. 1579-527 :

This letter is in response to the Request for Withdrawal of the Restriction Requirement mailed 15 April 2003. The delay in acting upon this petition is regretted.

#### BACKGROUND

This application was filed under 35 U.S.C. § 371 as the national stage filing of PCT/US99/17678.

In Paper No 5, mailed 27 November 2001, the Examiner restricted the claims into 13 Groups citing 35 USC 121 as the statutory basis for his restriction, as if the case was filed under 35 U.S.C. § 111 and not 35 USC § 371. Groups I-VI were drawn to polypeptide sequences encoding uricase enzymes comprising SEQ ID Nos. 2, 4, 8, 9, 10 and 11, respectively, Groups VII-XII were drawn to nucleic acids and vectors and host cells encoding the uricase enzymes, Group XIII was drawn to a method of making the enzymes of Groups I-VI less immunogenic by attaching PEG.

In Paper No. 7, filed 28 May 2002, Applicants elected Group V with traverse. The traversal was on the grounds that the case was filed under 35 U.S.C. § 371 and not 35 U.S.C. § 111 and so therefore a proper examination would be for unity of invention to apply under PCT Rule 13.1. In Paper No. 11, mailed 15 October 2002, the Examiner considered the traversal but found it not persuasive. The Examiner argued that although the form paragraphs used for Unity of Invention are different than for restriction the reasons would for restriction would be the same. The Examiner made the restriction Final.

In Paper No. 16 filed 14 April 2003, Applicants petitioned under 37 CFR 1.181 to withdraw the Restriction Requirement. The Petition argued that unity of invention was not applied to his invention as required under PCT Rule 13.1 and that the invention as now claimed had unity of invention.

## **DISCUSSION**

The current application was filed under 35 U.S.C. § 371, so a proper examination of the application would have led the Examiner to restrict the application according to 35 U.S.C. § 121 and § 372, identify why the groups did not share a special technical feature and therefore lacked unity of invention.

In view of facilitating a clear prosecution history the restriction set forth in Paper No. 5 is vacated and the following Lack of Unity requirement on the instantly pending claims is being set forth below:

Restriction is required under 35 U.S.C. § 121 and § 372.

This application contains the following groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 2-5 and 16-17, drawn to recombinant chimeric uricase proteins and methods of increasing the non-deleterious PEG attachment sites on uricase proteins.

Group II, claim(s) 6-15, drawn to polynucleotides, vectors and host cells encoding the recombinant chimeric uricase proteins.

The special technical feature of Group I is the recombinant chimeric uricase proteins.

The special technical feature of Group II is the polynucleotides, vectors and host cells encoding the recombinant chimeric uricase proteins.

4. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Miura et al., (of record) teaches a recombinant chimeric uricase protein which has been modified to insert one or more lysine residues wherein said protein has two or more mammalian amino acid sequences (see abstract in particular), thereby teaching Applicant's invention as presently recited in claim 2. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

## **DECISION**

This request for removal of the restriction requirement is **GRANTED-IN-PART**. The polypeptides will be examined together along with the method of use. However, claims directed to polynucleotides are not rejoined to the polypeptides because these inventions are not linked by a special technical feature which makes a contribution over the prior art.

Since Applicant has already received an Office action on the merits on one of the polypeptides, the examined claims in the next Office Action will be claims 2-5 and 16-17 directed to polypeptides and method of use. All of the polypeptides SEQ ID Nos. 2, 4 and 8-11 will be examined together. Since the next Office action will include an examination of polypeptides not previously examined, it will be made Non-Final.

The application is being forwarded to the examiner for action on claims 2-5 and 16-17, in response to Applicants' amendment filed 4-15-03 and the Decision of the Petition to include SEQ ID Nos. 2, 4 and 8-11 in the examination.

Since the Petition has been **GRANTED-IN-PART**, the fee of \$130.00 paid on 4/16/03 upon filing of this Petition will be refunded to applicants' deposit account number 14-1140.

Any request for reconsideration of this decision must be made by way of a renewed petition and must be filed within **TWO MONTHS** of the date of mailing of this decision in order to be considered timely.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.



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